



May 9, 2019

Request Number: 2019-3669

Anthony Roberts
Muckrock
Dept MR 70988 411A Highland Ave.
Sommerville, MA 02144

Subject of Request: Eric Poratz memos, emails inspection reports, etc.

Dear Mr. Roberts,

The Food and Drug Administration (FDA) has completed processing your request for records under the Freedom of Information Act (FOIA).

We are denying your entire request. Specifically, we are denying records from an open investigation.

The following exemption of FOIA, 5 U.S.C. 552, is the authority for denying you access to the non-disclosable material: Exemption (b)(7)(A) Records or information compiled for law enforcement purposes when disclosure could reasonably be expected to interfere with enforcement proceedings.

Section 5.31(g) of the implementing regulations of the Department of Health and Human Services (DHHS) is applicable to this denial. The regulations are contained in the Code of Federal Regulations (CFR), Title 45.

The following sections of the implementing regulations of FDA and reasons applicable to this denial are contained in the CFR, Title 21

- 20.64(a)(1) Records or information compiled for law enforcement purposes when disclosure could reasonably be expected to interfere with enforcement proceedings. Law enforcement proceedings may involve materials and information obtained from parties other than the target(s) of the proceeding

FDA's Regulations at CFR Part 20 are available at:

http://www.access.gpo.gov/nara/cfr/waisidx_04/21cfr20_04.html

You have the right to appeal this determination. By filing an appeal, you preserve your rights under FOIA and give the agency a chance to review and reconsider your request and the agency's decision. Your appeal must be mailed within 90 days from the date of this response, to: Agency Chief FOIA Officer, U.S. Department of Health and Human Services, Office of the Assistant Secretary for Public Affairs, Room 729H, 200 Independence Avenue, S.W., Washington, DC 20201; e-mail

U.S. Food and Drug Administration
5630 Fishers Lane, Room 1035
Rockville, MD 20857
www.fda.gov

FOIARequest@PSC.hhs.gov. Please clearly mark both the envelope and your letter or e-mail "FDA Freedom of Information Act Appeal."

If you would like to discuss our response before filing an appeal to attempt to resolve your dispute without going through the appeals process, please contact **Katherine Uhl at 301-796-8975**. You may also contact the FDA FOIA Public Liaison for assistance at: Office of the Executive Secretariat, US Food & Drug Administration, 5630 Fishers Lane, Room 1050, Rockville, MD 20857, E-mail: FDAFOIA@fda.hhs.gov.

If you are unable to resolve your FOIA dispute through our FOIA Public Liaison, the Office of Government Information Services (OGIS), the Federal FOIA Ombudsman's office, offers mediation services to help resolve disputes between FOIA requesters and Federal agencies. The contact information for OGIS is as follows: Office of Government Information Services, National Archives and Records Administration, 8601 Adelphi Road—OGIS, College Park, MD 20740-6001; telephone at 202-741-5770; toll free at 1-877-684-6448; or facsimile at 202-741-5769; e-mail at ogis@nara.gov.

If you have any questions, please contact Katherine Uhl at 301-796-8975.

Sincerely yours,

Sarah B. Kotler -S
Digitally signed by
Sarah B. Kotler -S
Date: 2019.05.09
07:40:12 -04'00'

Sarah Kotler
Director
Division of Freedom of Information